INDOFARMA

PURCHASING SPECIFICATION

Folic Acid, Microfine **(Asam Folat)**			
No. : RPB 181	**Rev : 01**	**Eff. date :** 170620	**Sign :**

1 **Quality** : USP 39, 2016
Internal Specification

2 **Additional Requirements**

2.1 Particle size : ≤ 45 µm Min.90.0%

2.2 Arrival Date : Max. 6 months from manufacturing date

3 **Certificate of Analysis from Manufacturer**

To be stated on the certificate

3.1 Manufacturer name and address

3.2 Product name , batch/lot number

3.3 Results of test and assays

3.4 Compliance with USP 39 and Internal Specification

3.5 Quality designation

3.6 Date of manufacturing, expiration (year-month) and date of released (year- month-day)

3.7 Approval/signature of QA/QC responsibility

4 Attached update Good Manufacture Practise Certificate

5 **Package**

Vat @ 25 kg, double plastic PE, with original seal (inside and outside) from manufacture.
To be stated on goods, label original from manufacture at primary and secondary package each.
Preserve in well – closed containers.

5 **Labelling**

To be stated on goods **label original from manufacturer**, packing list and invoice :

5.1 Name of manufacturer and address

5.2 Product name, batch/lot number, manufacturing and expiration date

5.3 Quality designation

5.4 Gross/net weight

5.5 Number of packages

6 **Reference Documents**

6.1 USP 39

6.2 Internal Specification

7 **History**

Purchasing specification revision of RPB 181 revision 00 with change in the quality of USP 35 to USP 39 and format document.

8 **Review**

This specification will be reviewed every 2 years or less (if necessary) by the Quality Control Manager, Research & Development Manager and Quality Assurance Manager.

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9 **Distribution**

In general, a copy of this specification is distributed to :

9.1 Procurement Dept.

9.2 Quality Control Dept.

10 **Approval**

Preparation steps	Position	Code	Signature	Date
Prepared by	Starting and Packaging Material Testing Assistant Manager	AM		170620
Checked by	Analytical Method Assistant Manager	LB		170620
Approved by	Quality Control Manager	AM		170620
	Research & Development Manager	LB		170620
	Quality Assurance Manager	PM		170620

11 **Review**

No.	Position	Date	Signature	Recommendation
1.	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			
2.	Quality Control Manager			
	Research & Development Manager			
	Quality Assurance Manager			